

September 9, 1998

This document was submitted to EPA by a registrant in connection with EPA's evaluation of this chemical and it is presented here exactly as submitted.

August 4, 1998

Ms. Ruby Whithers
Special Review and Reregistration Division (H7508W)
U.S. Environmental Protection Agency
401 M Street, NW
Washington, D.C. 20406

Subject: Isofenphos, Case 2345
Health Effects Division RED Chapter
Environmental Fate and Effects Division RED Chapter

Dear Ms. Whithers:

Bayer Corporation is responding to your request (via telephone to Ms. Julie Spagnoli of my staff) as to data Bayer intends to submit to the Agency in support of the active ingredient **isofenphos**.

Both of the subject draft RED chapters make reference to additional data which may be required to support the reregistration of isofenphos. However, it should be noted that these are draft chapters and that no formal data requirements have been issued by the Agency. Thus, Bayer is not in position at this time to formally commit to submission of any of these data, pending an actual data call-in. Specifically in the case of the EFED assessment, final data requirements will be determined based on the use patterns eligible for reregistration. Determination of uses eligible for reregistration is pending a definitive risk assessment of existing uses. The risk assessment included in the draft HED chapter utilized only a screening assessment for occupational and residential exposure.

The screening evaluations for residential exposure are based on extremely conservative default assumptions and are intended to identify **potential** risks. The Agency has stated its current position regarding the use of these models as "Risks are considered to be of no concern if model estimates show insignificant risks. Risks are considered to be of potential concern if model estimates show significant risks." The Agency has also stated that the use of these models may greatly overestimate the actual exposure.

We strongly believe this is the case for isofenphos and EPA's risk evaluation of isofenphos is a very preliminary, extremely conservative assessment based on default assumptions (generally unrealistic) and little or no actual data. Isofenphos has a long and safe use history in the residential and commercial turf market. The safety of isofenphos, was extensively evaluated by Bayer and the EPA prior to its initial registration in 1980 and on a continuing basis since then. Bayer is not aware of, nor has the EPA indicated the existence of, any evidence that would bring into question the safety of isofenphos under current actual use conditions.

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The risks estimated by EPA are in no way reflective of those associated with actual use and do not take advantage of available data. Based on existing exposure data and isofenphos use information, Bayer estimates aggregate "day of application" margins of exposure (MOEs) for adults, children 1-6 years-old and children < 1 year-old to be 3049, 1166 and 1063, respectively. These MOEs for adults and children are more than 270,000 and 96,000 times higher, respectively, than those estimated by EPA. These MOE's are based on the same conservative exposure data and assumptions used by EPA to evaluate the aggregate risks associated with pyrethroid use on residential turf in November, 1997. (Synthetic Pyrethroids: Generic Methodology for Non-Dietary and Aggregate Risk Assessment, J. H. Driver, *et. al.*, submitted with letter to G. LaRocca dated 9/15/97, no MRID yet assigned) In addition, EPA has recommended in the hazard identification summary issued subsequent to the draft HED chapter that the extra 10X safety factor be removed for isofenphos, thus the MOE's indicated above are more than adequate (>300) for the determination of reasonable certainty of no harm from the current uses of isofenphos. A refined risk assessment should be done for isofenphos using available information and the refined hazard identification.

Lastly, it should be noted that additional data that could be used to further refine this assessment are being generated by the Outdoor Residential Exposure Task Force in conjunction with scientists from EPA, the California Department of Pesticide Regulation and Health Canada. However, these data are not yet available.

Please contact Ms. Julie Spagnoli of my staff at (816) 242-2164 for any further information.

Sincerely,

John S. Thornton
Director
Product Registrations and Regulatory Affairs

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